

REMARKS/ARGUMENTS

Claims 1-166 have been examined. Claims 1, 2, 11-18, 20-22, 26-28, 31, 32, 35, 45-47, 69, 71, 73, 74, 76, 79, 84, 91, 97, 99, 101, 132, 136, and 137 have been amended. Claims 3-10, 19, 24, 25, 29, 30, 33, 34, 36-44, 50-68, 70, 72, 75, 77, 78, 86-90, 92-96, 102-106, 108-131, 145, 146, and 156-166 have been canceled.

As an initial matter, Applicants request the status of claims 20, 48, 137, and 139 as these dependent claims were not addressed in the Office Action of July 27, 2004. It is further requested that any further action issued in this case be made non-final so that Applicants may adequately address these claims.

Applicants also request that the Examiner send confirmation of the consideration of the references cited in the Information Disclosure Statement filed by Applicants on June 25, 2002, specifically Cite Nos. BK-CO.

Re-examination and reconsideration of pending claims 1, 2, 11-18, 20-23, 26-28, 31, 32, 35, 45-49, 69, 71, 73, 74, 76, 79-85, 91, 97-101, 107, 132-144, and 147-155 are respectfully requested.

Restriction Requirement

Applicants have canceled claims 3-10, 24, 25, 33, 34, 36-44, 50-68, 75, 77, 78, 86-90, 92-96, 102-106, 108-131, 145, 146, and 156-166 without prejudice pursuant to a restriction requirement. Applicants reserve the right to pursue patent protection for these inventions in a subsequently filed application.

Claim Objections

As requested by Examiner, Applicants have amended claims 14, 15, 31, 32, and 136 to correct informalities. Claims 19, 29, and 30 have been canceled. With respect to claim 83, Applicants respectfully disagree. Claim 83 recites a numerical range from .001 inches to .014 inches, which is less than claim 82 from which it depends, which recites a range from .001 inches to .1 inches. Accordingly, withdrawal of these objections is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claims 12, 18-20, and 137 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claims 12, 20, and 137 have been amended as requested by Examiner so that they are now clear. Claim 19 has been canceled. Accordingly, withdrawal of these 35 U.S.C. § 112, second paragraph rejections is respectfully requested.

Substantive Rejections

Independent claims 1 and 2 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No 4,655,746 issued to Daniels et al. Dependent claim 72 has been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 5,195,978 to Schiffer in view of Daniels et al. Such rejections are traversed in part and overcome in part as follows.

Independent claims 1 and 2 have been amended to include the limitation of dependent claim 72. Claim 1 now recites an intravascular balloon catheter (10") comprising a catheter body (12) and a first balloon structure (26). The catheter body (12) has a proximal end, a distal end, and a guidewire lumen (20) therebetween. The first balloon structure (26) has a passage (41) which is slidably receivable over the catheter body (12). In particular, claim 1 now also requires that the first balloon structure (26) also have an axial groove (102) along at least a portion of the structure (26) and the passage (41) to removably receive at least a portion of the catheter body (12). Claim 2 has been similarly amended. This distinct and separate axial groove limitation has not been shown or suggested in any of the cited art references, alone or in combination.

The Daniels et al. reference is directed at a catheter device as shown in Figure 3. Significantly, this reference fails to remotely teach or suggest any axial groove elements as now required by claims 1 and 2. With respect to the Schiffer reference, Figures 1-3 illustrate a conventional rapid exchange over-the-wire catheter for use with a guidewire, not a catheter body having a guidewire lumen as required by claims 1 and 2. Further, the Schiffer catheter has a breakaway feature or tear strip 32 that allows for separation of the guidewire 18 from the guidewire lumen 30 of the catheter 10. At best, Schiffer teaches that the guidewire lumen 30 may be opened along the tear strip 32. This reference fails to teach or suggest the two distinct and separate elements of the balloon structure (26), namely a passage (41) and an axial groove

(102), much less an axial groove (102) that extends along at least a portion of the passage (41) as currently claimed.

Applicants request if the present rejection is maintained, the Examiner show or explain where the Schiffer reference teaches or suggest the distinct structural limitation of an axial groove that extend along at least a portion of the passage. Absent a showing in the cited art of record for this distinct and structural difference, Applicants request the withdrawal of these rejections and allowance of independent claims 1 and 2 (and the claims which depend therefrom).

With respect to independent claim 132, it has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Schiffer. Independent claim 132 has also been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,395,335 issued to Jang. Such rejections are traversed in part and overcome in part as follows.

Independent claim 132 has been amended. Claim 132 is directed to an intravascular balloon catheter that now requires in part, similar to independent claims 1 and 2, an axial groove formed over at least a portion of the length of the balloon structure shaft and along a length of the passage to removably receive at least a portion of the elongate body.

This element has not been remotely shown or suggested in the Schiffer reference for similar reasons as discussed above with respect to claims 1 and 2. With respect to the Yang reference, this reference discloses a catheter system for guidewire exchange. In particular, the Yang catheter 10 has a guidewire lumen 20 having guidewire removing means 40 so that the guidewire 50 can be removed from the guidewire lumen 20 of the catheter 10 as shown in Figures 2-3. At best, Yang teaches that the guidewire lumen 20 may be opened along the perforation 40. This reference fails to teach or suggest the two distinct and separate elements of the balloon structure (26), namely a passage (41) and an axial groove (102), much less an axial groove (102) that extends along at least a portion of the passage (41) as currently claimed.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). As *prima facie*

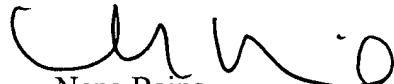
anticipation has not been established, Applicants request the withdrawal of these § 102 rejections and allowance of independent claim 132 (and the claims which depend therefrom).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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